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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/140,886	08/26/1998	HERBERT M. WILSON	N1205-003	9239

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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/140,886	Applicant(s) WILSON ET AL.	
	Examiner David T. Fox	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 November 2003 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-22 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claims are broadly drawn to methods of introducing uncharacterized DNA into plants. The uncharacterized DNA has not been evaluated for its sequence, the presence of any particular gene or genes, or its ability to confer any particular trait to the recipient transformed plant. During the personal interview of 16 October 2002, Applicant reiterated that the method was intended to introduce genetic diversity in particular plant varieties, which diversity could be utilized as a source of yet-to-be discovered genes encoding agronomic traits of interest, for use in a future breeding program. However, this intended use of the plants transformed with uncharacterized DNA would require carrying out further research to evaluate said transformed plants for

the exhibition of even one of a multitude of non-exemplified agronomic traits, for the selection of said plants, for the crossing of said plants with themselves or other plants, and for the selection of plants exhibiting the same traits (if any) in the progeny generation, etc. Such further research indicates that the claimed method currently does not possess a "real world" use.

See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966) wherein a research utility was not considered a "substantial utility".

Furthermore, agronomic traits such as yield are governed by the action of multiple genes on many chromosomes, each of which has a small additive effect, so that transferring only one piece of uncharacterized DNA from one chromosome would be unlikely to confer any substantial increase in yield. It is also known in the art that many genes are only expressed in particular genetic backgrounds, so that introducing uncharacterized DNA from sorghum into maize may not result in the expression of any agronomically desirable trait, even if the uncharacterized DNA in fact possessed a gene that conferred an agronomically desirable trait when expressed in the native sorghum. Thus the claims lack a substantial utility.

Finally, since the claims are not drawn to any particular agronomic trait, and since they encompass a multitude of unspecified and non-exemplified traits, they do not possess a specific utility.

Claims 1-22 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted

utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1-22 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 2 and 4-5 of the last office action.

Claims 1-22 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated on page 2 of the last office action.

Claims 1-22 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, regarding the recitation of "uncharacterized" in claims 1 and 15, as stated on pages 2 and 7 of the last office action.

Claims 1-2 and 8-9 remain rejected under 35 U.S.C. 102(b) as being anticipated by EP 299,552 (SOLVAY), as stated on pages 2 and 7 of the last office action.

Claims 1, 4, 8 and 11 remain rejected under 35 U.S.C. 102(b) as being anticipated by Korohoda et al, as stated on page 2 of the last office action.

Claims 1, 4, 6, 8, 11 and 13 remain rejected under 35 U.S.C. 102(b) as being anticipated by Zhou et al, as stated on page 3 of the last office action.

Claims 1, 4, 6, 8, 11 and 13 remain rejected under 35 U.S.C. 102(b) as being anticipated by Soyfer et al in light of Turbin et al, as stated on page 3 of the last office action.

Claims 1-22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over EP 299,552 (SOLVAY), as stated on page 3 of the last office action.

No claim is allowed.

Applicant's arguments filed 25 November 2003 have been fully considered but they are not persuasive.

Applicant urges that the written description rejection and enablement rejections are improper, given the teachings of the Wilson and Stine declarations submitted on 20 February 2001 (response, page 2, top paragraph). Applicant further argues that the absence of regulatory DNA on the uncharacterized DNA fragment will not result in the production of plants with improved agronomic characteristics (page 2 of the response, penultimate paragraph). Applicant also urges that the Holl et al and Kamra et al teachings have not been substantiated by subsequent workers (page 2, bottom paragraph).

The Examiner maintains that the Wilson declaration merely demonstrates the obtention of corn plants transformed with the uncharacterized sorghum DNA *bounded by two selectable marker genes*; while the Stine declaration merely *opines* that techniques are available for identifying and evaluating transformed plants and their progeny containing exogenous uncharacterized DNA and exhibiting improved agronomic traits. However, neither declaration demonstrates that the exemplified

uncharacterized sorghum DNA actually conferred any trait, improved or otherwise, to the recipient maize plants. Thus, the Wilson declaration does not teach *how to use* the resultant plants. In addition, the Stine declaration, executed by an Officer in the company which employs Applicants, is merely an opinion declaration executed by an interested party, and is thus not probative. It is also noted that *the instant specification* does not provide any guidance for assaying transformed plants for a multitude of agronomic traits encompassing drought tolerance, standability, or improved yield, etc., which are complexly inherited and whose expression varies greatly in different growing environments.

Furthermore, neither declaration addresses the deficiencies set forth in the written description rejection, namely, that the specification does not adequately describe even the exemplified "uncharacterized DNA" from sorghum in terms of its sequence or genes present, that the specification does not identify any structural features of the "uncharacterized DNA" which would be responsible for its alleged (and unproven) function of conferring improved agronomic traits, and that the specification clearly does not demonstrate reduction to practice of any other "uncharacterized DNA" from any other donor plant species which would confer improved agronomic characteristics to a recipient plant. Given the single disclosure of an "uncharacterized DNA fragment" from a single plant species; the breadth of the claims which encompass any donor plant species from a multitude of unrelated species, genera, and families; and the lack of guidance as discussed above and previously; the specification does not provide an adequate written description of the genus as broadly claimed so that one skilled in the

art would recognize Applicant to have been in possession of the claimed invention. See *University of California v. Lilly* cited previously.

The Stine declaration does not provide any experimental data, or describe any piece of DNA, "uncharacterized" or not. The Wilson declaration does not teach any structural features of the *uncharacterized* DNA, i.e. conserved sequences, which are correlated with a particular function, i.e. improved disease resistance, improved stress resistance, improved insect resistance, superior yield, etc., as recited on page 3 of the response of 25 November 2003, top paragraph). Thus, neither the specification nor the Wilson declaration provide an adequate written description of the uncharacterized DNA or a method for its use. See *University of California v. Lilly* and the Written Description Guidelines cited previously.

See also MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Even if the Wilson declaration or the instant specification did adequately describe the *exemplified sorghum-derived "uncharacterized DNA"*, it does not provide an adequate written description of the *broadly claimed genus, which encompasses any piece of DNA of any length and of any sequence and from any plant species*. The

uncharacterized DNA could be from unrelated plants such as oak, tobacco, palm, onion, gingko, cacti, corn, vanilla, orchid, etc., which exhibit very little structural sequence conservation, and very little morphological similarities. Oaks look and act very differently from orchids. Thus, the uncharacterized DNA over the broadly claimed genus would share little structural similarity (i.e. conserved DNA sequence) or functional similarity (i.e. ability to confer a particular trait, such as trunk thickness in oak versus flower color in orchid). The uncharacterized DNA could be as little as one base pair in length, up to an entire genome which encompasses tens of thousands or more base pairs in length. The broadly claimed genus is completely uncharacterized with respect to *any degree of conservation of structure or function, or any degree of correlation between structure and function*, as required by the Written Description Guidelines, the cited case law, and the MPEP.

Regarding the enablement rejection, the Examiner maintains that the mere demonstration of integration of the "uncharacterized donor DNA" by the Wilson declaration does not remedy the unpredictability inherent in the *expression* of uncharacterized foreign DNA in cells of heterologous plant species, as set forth in previous Office actions. In addition, the unpredictability inherent in the maintenance of large stretches of "uncharacterized donor DNA" from heterologous or homologous species, when introduced into plants by a multitude of non-exemplified methods, as evidenced by Holl et al and Karma et al, has not been addressed by either declaration. The *allegations* of the Stine declaration are insufficient to overcome the *evidence* of unpredictability set forth by the Examiner in the form of scientific reasoning and

publications. Applicant's admission of this unpredictability, regarding the necessity of native regulatory sequences on the "uncharacterized DNA", is noted above.

The scope of the claims, which broadly read on any uncharacterized DNA from any plant source, introduced into any other plant by any method, does not correspond to the conditions used in the Wilson declaration to obtain successful *integration* of the uncharacterized DNA, i.e. the use of *characterized* selectable marker genes on either side of the uncharacterized DNA, in order to select plants which contain and maintain the uncharacterized DNA. Given the tendency of large pieces of DNA to be degraded in transformed plants as discussed above and previously, in the absence of any means of selection, the uncharacterized DNA would be quickly lost from the transformed plants, and would thus be unavailable for any further use by Applicants in a breeding program.

Regarding Applicant's assertions that the results of Holl et al and Karma et al have not been substantiated by later workers, the Examiner disagrees. Holl et al and Karma et al demonstrated that large stretches of "uncharacterized DNA" were not maintained in plants into which they had been introduced. Other workers did not publish contrary results demonstrating success. If anything, subsequent workers' silence on the matter only confirms the teachings of Holl et al and Karma et al that the technique remains inoperable. See also Applicant's arguments on pages 4-5 of the response of 20 September 2002, traversing the prior art rejections newly set forth in the last office action, which arguments support the Examiner's characterization of Holl et al and Karma et al. Finally, the claim breadth encompasses the techniques utilized by each of Holl et al and Karma et al.

Applicant urges that "uncharacterized" is not indefinite because it has an art-recognized meaning. The Examiner maintains that the specification is silent with respect to the definition of this term, and that no other evidence of its art-recognized definition has been presented. It is unclear whether the "lack of characterization" is with respect to complete sequence information over the entire length of the piece of DNA, function or sequence of any putative protein or transcription product encoded by a gene somewhere on the DNA, the length of the piece of DNA, the presence of restriction fragments or other domains or consensus sequences in an otherwise unsequenced piece of DNA, etc. All of these criteria would be recognized by the skilled artisan as potential areas for characterization or uncharacterization of a piece of DNA, and the specification provides no guidance regarding which of these criteria were intended. In the absence of such clarification, the skilled artisan would not know what was being claimed, and would not be able to recognize the claimed invention or distinguish it from what was taught in the prior art.

Applicant's comments regarding "improved agronomic characteristics" are deemed moot in view of the failure of the Examiner to object to this term. Furthermore, such "improved agronomic characteristics" are also conferred by *characterized, sequenced, specific isolated genes* such as the potato gene encoding a proteinase inhibitor. Thus, defining a piece of DNA solely in terms of what traits it confers to a plant is insufficient to distinguish between "characterized" and "uncharacterized".

Applicant's attempt on page 1 of the response, bottom paragraph, to define "uncharacterized" as a lack of sequencing of a DNA sequence, contradicts Applicant's

reliance upon of the results Wilson declaration, which results rely upon the introduction of *characterized* (i.e. isolated and sequenced) selectable marker genes into transformed plants. The specification does not provide any guidance to address this inconsistency and confusion.

Applicant urges that the prior art rejections under 35 USC 102 or 103 over SOLVAY are improper, given the failure of the reference to teach or suggest "the use of uncharacterized DNA to generate transgenic plants for use in a breeding program" (page 3 of the response, top paragraph). The Examiner maintains that this intended use, merely recited in the preamble, is not given patentable weight. Every element of the body of the claims is taught by SOLVAY.

Applicant urges that all of the prior art rejections are improper, given the failure of the macroinjection-mediated plant transformation techniques employed therein to be reproduced or substantiated by subsequent workers, and the lack of molecular and genetic evidence presented by the references. The Examiner maintains that such an assertion is not probative. A declaration by a disinterested party attesting to the inoperability or lack of repeatability of the prior art methods would be more probative. In addition, Zhou et al do teach the use of molecular evidence, in the form of DNA probes, to demonstrate the incorporation of the uncharacterized DNA into the genome of the recipient plant (see, e.g., page 248, second paragraph).

Furthermore, the claims are not drawn to the stable, heritable maintenance of the "improved agronomic characteristics" over several generations (i.e. "genetic evidence"). The claims are also not drawn to the particular method of transformation

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utilized by Applicant to obtain stable integration of the uncharacterized DNA. The claims are also not drawn to the donor and recipient plant species utilized by Applicant to demonstrate unexpected results. See In re Lindner, 173 USPQ 356 (CCPA 1972) and In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

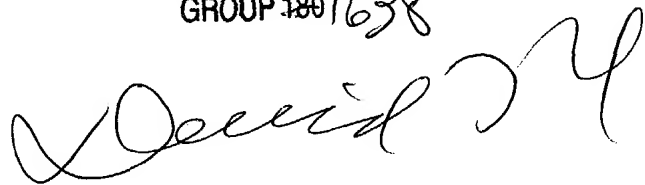
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

March 2, 2004

DAVID T. FOX
PRIMARY EXAMINER
GROUP 1801638

A handwritten signature in black ink, appearing to read "David T. Fox", is written over the typed name and group number.